Application No.: 10/621,711

Office Action Dated: January 16, 2008

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application. Listing of Claims:

1-162. (Canceled)

- 163. (Currently amended) A transdermal <u>hormone</u> delivery system comprising a backing layer and an adhesive polymer matrix containing progestin and estrogen hormones to be transdermally delivered affixed to the backing layer, wherein the adhesive polymer matrix comprises:
 - (a) an adhesive polymer;
 - (b) a humectant;
- (c) a combination of skin permeation enhancing agents consisting essentially of, on a final percentage by weight of the adhesive polymer matrix after fabrication of the system, from about 4% to about 12% dimethyl sulfoxide; from about 4.2% to about 12.6% a fatty (C₈-C₂₀) alcohol ester of lactic acid; from about 0.7% to about 2.3% lower (C₁-C₄) alkyl ester of lactic acid; and from about 3% to about 9% capric acid;
 - (d) a progestin; and
 - (e) an estrogen

an adhesive polymer, a humectant, the progestin, the estrogen, and a combination of skin permeation enhancing agents comprising dimethyl sulfoxide, a fatty (C₈-C₂₀) alcohol ester of lactic acid, a lower (C₁-C₁) alkyl ester of lactic acid, and capric acid, wherein the capric acid is present in an amount between about 3% and about 9% by weight of the adhesive polymer matrix.

- 164. (Previously presented) The transdermal delivery system of claim 163, wherein the adhesive polymer is a polyacrylate copolymer, a polyisobutylene or a silicone adhesive.
- 165. (Previously presented) The transdermal delivery system of claim 164, wherein the polyacrylate copolymer comprises a 2-ethylhexyl acrylate monomer.

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166. (Previously presented) The transdermal delivery system of claim 165, wherein the polyacrylate copolymer further comprises about 3 to 60% w/w vinyl acetate.

- 167. (Previously presented) The transdermal delivery system of claim 163, wherein the humectant comprises polyvinylpyrrolidone.
- 168. (Previously presented) The transdermal delivery system of claim 167, wherein the humectant comprises a polyvinylpyrrolidone copolymer.
- 169. (Previously presented) The transdermal delivery system of claim 168, wherein the humectant is a polyvinylpyrrolidone/vinyl acetate copolymer.
- 170. (Previously presented) The transdermal delivery system of claim 169, wherein the polyvinylpyrrolidone is formulated in an amount of about 60% w/w and the vinyl acetate is formulated in an amount of about 40% w/w in the polyvinylpyrrolidone/vinyl acetate copolymer.
- 171. (Previously presented) The transdermal delivery system of claim 163, wherein the fatty alcohol ester of lactic acid is lauryl lactate.
- 172. (Previously presented) The transdermal delivery system of claim 163, wherein the lower alkyl ester of lactic acid is ethyl lactate.
- 173. (Previously presented) The transdermal delivery system of claim 163, wherein the progestin is levonorgestrel.

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- 174. (Previously presented) The transdermal delivery system of claim 163, wherein the estrogen is ethinyl estradiol or 17 β -estradiol.
- 175. (Previously presented) The transdermal delivery system of claim 173, which, when applied to the skin of a human, once each week, consecutively over a period of three or more weeks, deliver *in vivo* an average serum concentration of over 1000 pg/ml of levonorgestrel.
- 176. (Currently amended) The transdermal delivery system of claim 163, wherein the adhesive polymer matrix comprises about 12% to about 36% more than 10% and less than about 30% by weight of the combination of skin permeation enhancing agents.
- 177. (Previously presented) The transdermal delivery system of claim 163, wherein the adhesive polymer matrix comprises about 18% to about 30% by weight of the combination of skin permeation enhancing agents.
- 178. (Previously presented) The transdermal delivery system of claim 163, wherein the adhesive polymer matrix comprises about 21% to about 27% by weight of the combination of skin permeation enhancing agents.
- 179. (Previously presented) The transdermal delivery system of claim 163, wherein the adhesive polymer matrix is formulated by combining the adhesive polymer, the humectant, the progestin, the estrogen, and about 10% to about 30% by weight of the combination of skin permeation enhancing agents.
- 180. (Previously presented) The transdermal delivery system of claim 163, wherein the adhesive polymer matrix is formulated by combining the adhesive polymer, the

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humectant, the progestin, the estrogen, and about 13% to about 27% by weight of the combination of skin permeation enhancing agents.

- 181. (Previously presented) The transdermal delivery system of claim 163, wherein the capric acid is present in an amount between about 4% and about 8% by weight of the adhesive polymer matrix.
- 182. (Previously presented) The transdermal delivery system of claim 163, wherein the capric acid is present in an amount between about 5% and about 7% by weight of the adhesive polymer matrix.
- 183. (New) The transdermal delivery system of claim 163, wherein the dimethyl sulfoxide is present in an amount between about 5% and about 11% by weight of the adhesive polymer matrix.
- 184. (New) The transdermal delivery system of claim 163, wherein the dimethyl sulfoxide is present in an amount between about 6% and about 10% by weight of the adhesive polymer matrix.
- 185. (New) The transdermal delivery system of claim 163, wherein the fatty (C_{8} - C_{20}) alcohol ester of lactic acid is present in an amount between about 5.2% and about 11.6% by weight of the adhesive polymer matrix.
- 186. (New) The transdermal delivery system of claim 163, wherein the fatty (C₈-C₂₀) alcohol ester of lactic acid is present in an amount between about 6.2% and about 10.6% by weight of the adhesive polymer matrix.

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187. (New) The transdermal delivery system of claim 163, wherein the lower (C₁-C₄) alkyl ester of lactic acid is present in an amount between about 1.0% and about 2.0% by weight of the adhesive polymer matrix.

188. (New) The transdermal delivery system of claim 163, wherein the lower (C₁-C₄) alkyl ester of lactic acid is present in an amount between about 1.2% and about 1.8% by weight of the adhesive polymer matrix.